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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,180	01/21/2004	Muthaiyyan Esakkil Kannan	1276-37	4776
7590	11/19/2008		EXAMINER	
Michael E. Carmen, Esq. M. CARMEN & ASSOCIATES, PLLC Suite 400 170 Old Country Road Mineola, NY 11501			DICKINSON, PAUL W	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			11/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/762,180	<b>Applicant(s)</b> KANNAN ET AL.
	<b>Examiner</b> PAUL DICKINSON	<b>Art Unit</b> 1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 August 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,7,9,22-24 and 29-54 is/are pending in the application.
- 4a) Of the above claim(s) 6-7, 9, 22-24, 30-31, 33-37, 39, and 41 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3-5,29,32,38,40 and 42-54 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review ("PTO-544")
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

Applicant's arguments, filed 8/4/2008, have been fully considered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

No prior art against the elected species was found. The search was therefore expanded to nonelected embodiments, which is set forth in the prior art rejection below. The search was not extended to the entire scope of the claims since prior art was found against the generic claim.

***New Grounds of Rejection******Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 38 recites "wherein said composition further comprises an optional coating which is designed for modification of drug release." Claim 40 recites "wherein said composition further comprises an optional coating which is not designed for modification of drug release." It is unclear what coatings are encompassed by these claims. A coating may not be designed for drug modification of drug release, but the

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coating may still unintentionally provide such modification by happenstance. Similarly, a coating may be designed for the modification of drug release, but the coating may unintentionally fail to provide such modification. The Examiner recommends claim language which does not include the term "designed" but instead simply states that the coating does or does not provide modification of drug release.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 38, 40, and 42-54 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6039980 ('980). '980 discloses a solid oral controlled release pharmaceutical composition comprising (a) a therapeutically effective amount of a pharmaceutically active ingredient; and (b) a controlled release modifying complex wherein said complex comprises: (i) galactomanna gum (a

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primary release modifying agent); (ii) an ionizable gel strength enhancing agent (a secondary release modifying agent); and (iii) an inert pharmaceutical filler (an auxiliary release modifying agent) wherein said primary, secondary and auxiliary release modifying agents are present in amounts that synergistically extend the release of the pharmaceutically active ingredient, and further wherein component (a) is admixed with components (i), (ii) and (iii) of component (b) (see abstract; col 1, line 47 to col 2, line 67). The inert pharmaceutical filler may be a starch (see col 4, line 20). The dosage form may be coated (see col 4, lines 53-55).

Claims 1, 3-5, 29, 32, 38, 40 and 42-54 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by US 6365590 ('590). '590 discloses a solid controlled release pharmaceutical composition comprising (a) a therapeutically effective amount of a pharmaceutically active ingredient; and (b) a controlled release modifying complex wherein said complex comprises: (i) low molecular weight polyethylene glycol (a primary release modifying agent); (ii) high molecular weight polyethylene glycol (a secondary release modifying agent); and (iii) a powdered carrier, such as starch (an auxiliary release modifying agent) wherein said primary, secondary and auxiliary release modifying agents are present in amounts that synergistically extend the release of the pharmaceutically active ingredient (it is further noted that the coating of claims 38 and 40 are optional), and further wherein component (a) is admixed with components (i), (ii) and (iii) of component (b) (see col 10, line 21 to col 11, line 40).

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'590 does not teach oral administration of the composition. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the present case, the composition taught by '590 is fully capable of being administered orally.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson  
Examiner  
AU 1618

November 17, 2008